January 9, 2001

Lorraine E. Twerdok, Ph.D., DABT
Manager, Health Sciences
American Petroleum Institute
1220 L Street, Northwest
Washington, DC 20005-4070

Dear Dr. Twerdok:

The Office of Pollution Prevention and Toxics is transmitting EPA's comments on the robust summaries and test plan for the Petroleum Gases category, sent August 15, 2000. I commend the American Petroleum Institute (API) Petroleum HPV Testing Group for their commitment to the HPV Challenge Program and encourage you to take appropriate steps to make your submission a successful contribution.

EPA reviews test plans and robust summaries to determine whether the reported data and test plans will provide the data necessary to adequately characterize each SIDS endpoint. On its Chemical RTK HPV Challenge Program website EPA has provided guidance for determining the adequacy of data and preparing test plans used to prioritize chemicals for further work.

API has devised a category approach for 161substances. As detailed in the attached Comments, EPA believes that API needs to better explain the reasons for its approach in such areas as determining the size and boundaries of the category, description of category members, selection of test substances, and showing how the data will be applied to untested category members. Some details of the planned testing are inadequate. The robust summaries for health and environmental effects are also inadequate.

The submission cites the "EPA test rule" as a source of data on 1,2-butadiene and 1-pentene. EPA proposed a test rule for HPV chemicals on December 26, 2000 (FR 65, 81657-81685) which does not include these two chemicals. The test plan needs to address these substances more directly.

As with other submissions where the available data are either inadequate or insufficiently documented, this case will remain open until adequate documentation is in hand.

API proposes to perform *in vivo* studies with five test substances for chromosomal effects (mouse micronucleus assay). In order to conform to the intent of EPA's October 14, 1999, letter to sponsors, which encourages the use of *in vitro* genotoxicity tests unless known chemical properties preclude their use, we ask API to elaborate why it considers *in vivo* testing necessary in this case.

Of the six chemicals proposed for testing, three (butane, isobutane and propane) are listed as Generally Recognized as Safe (GRAS) by the U.S. Food and Drug Administration (FDA). FDA publicly available files may contain toxicity data to support these claims.

EPA will post this letter and the attached Comments on the Chemical RTK web site within the next few days. As noted in the comments, we ask that API advise the Agency, within 90 days of the posting on the Chemical RTK website, of any modifications to its submission.

If you have any questions about this response, please contact Richard Hefter, Chief of the HPV Chemicals Branch, at 202-260-3470. Submit general questions about the HPV Challenge Program through the Chemical RTK web site comment button or through the TSCA Assistance Information Service (TSCA Hotline) at (202) 554-1404. The TSCA Hotline can also be reached by e-mail at tsca-hotline@.epa.gov.

I thank you for your submissions and look forward to your continued participation in the HPV Challenge Program.

Sincerely,

Oscar Hernandez, Director
Risk Assessment Division

Attachment

cc: W. Sanders
C. Auer
M. Weber
A. Abramson